



**WA Pharmacy Quality Assurance Commission
2020 Responsible Pharmacy Manager
Pharmacy Self-Inspection Worksheet
USP 795 – Nonsterile Compounding Addendum**

ATTENTION: Responsible Pharmacy Manager

Washington law holds the responsible manager and all pharmacists on duty responsible for ensuring pharmacy compliance with all state and federal laws governing the practice of pharmacy. Failure to complete this report within the month of March or within 30 days of becoming responsible manager (as required by WAC 246-945-005) may result in disciplinary action. **The following addendum is required to be filled out and kept on file with the General Pharmacy Self-Inspection Worksheet. Do not send to the Commission office.**

The primary objective of this report, and your self-inspection, is to provide an opportunity to identify and correct areas of non-compliance with state and federal law. This worksheet does not replace *U.S. Pharmacopeia (USP) <795> Pharmaceutical Compounding – Sterile Preparations*. (NOTE: Neither the self-inspection nor a Commission inspection evaluates your complete compliance with all laws and rules of the practice of pharmacy.)

By answering the questions and referencing the appropriate laws/rules/CFR provided, you can determine whether you are compliant with many of the rules and regulations. If you have corrected any deficiencies, please write corrected and the date of correction by the appropriate question.

For additional guidance on the self-inspection addendum, please see [Guidance Document #61 – United States Pharmacopeia General Chapter <795> - Nonsterile Compounding – Information](#).

Date responsible manager/change of responsible manager inspection was performed: _____

Signature of responsible pharmacy manager: _____

Questions highlighted in blue are questions that will be focused on during routine pharmacy inspections.

General Rule Reference - Applies to all questions through worksheet.

RCW 18.64.270(2) "Any medicinal products that are compounded for patient administration or distribution to a licensed practitioner for patient use or administration shall, at a minimum, meet the standards of the official United States pharmacopeia as it applies to nonsterile products and sterile administered products."

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
Training & Training Procedures						
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1	Are all licensed pharmacy personnel involved in compounding properly trained for the type of compounding they perform? *USP recommends annual evaluations of personnel training.*	USP Chapter 795 Categories of Compounding - "Compounders shall acquire and maintain knowledge and skills in all areas (e.g. dosage, form, patient population, and medical specialty) for which they compound. USP Chapter 795 - Training "All personnel involved in the compounding, evaluation, packaging, and dispensing of compounded preparations shall be properly trained for the type of compounding conducted. It is the responsibility of the compounder to ensure that a training program has been implemented and that it is ongoing. " *Compounder in this reference can be either a pharmacist or a pharmacy technician.*	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2	Do training procedures require all pharmacy personnel who compound to read and be familiar with <USP 795>?	USP Chapter 795 - "Steps in the training procedure include the following: • All employees involved in pharmaceutical compounding shall read and become familiar with this chapter. They should also be familiar with the contents of the USP Pharmacists' Pharmacopeia and other relevant publications, including how to read and interpret MSDSs."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	3	Do training procedures require all pharmacy personnel who compound to read and be familiar with your pharmacy's procedures related to compounding?	USP Chapter 795 - "Steps in the training procedure include the following: • All employees shall read and become familiar with each of the procedures related to compounding, including those involving the facility, equipment, personnel, actual compounding, evaluation, packaging, storage, and dispensing."	

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Compliant			#		Rule Reference	Notes/Corrective Actions	
Yes	No	N/A					
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	4	Do training procedures include hazardous drug training if hazardous drugs are handled in the pharmacy?	USP Chapter 795 - "Steps in the training procedure include the following: All personnel who compound hazardous drugs shall be fully trained in the storage, handling, and disposal of these drugs. This training shall occur before preparing or handling hazardous drugs."		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	5	Do training procedures require all training activities to be documented by the responsible manager?	USP Chapter 795 - "Steps in the training procedure include the following: • All training activities shall be documented. The compounder shall meet with employees to review their work and answer any questions the employees may have concerning compounding procedures."		
			6	Do training procedures include the following?	USP Chapter 795 - Training "Steps in the training procedure include the following:		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		a	Demonstration and observation of proper procedures and knowledge of procedures.	USP Chapter 795 - Training "• The compounder shall demonstrate the procedures for the employee and shall observe and guide the employee throughout the training process. The employee will then repeat the procedure without any assistance from, but under the direct supervision of, the compounder. • When the employee has demonstrated to the compounder a verbal and functional knowledge of the procedure, then and only then will the employee be permitted to perform the procedure without direct supervision. However, the compounder should be physically present and shall approve all ingredients and their quantities and the final preparation." *Compounder in this reference can be either a pharmacist or a pharmacy technician.*	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		b	Requiring signatures on training documentation	USP Chapter 795 - Training "• When the compounder is satisfied with the employee's knowledge and proficiency, the compounder will sign the documentation records to show that the employee was appropriately trained." *Compounder in this reference can be either a pharmacist or a pharmacy technician.*	

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Compliant			#			Rule Reference	Notes/Corrective Actions
Yes	No	N/A					
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		c	Pharmacist monitoring of employees work	USP Chapter 795 - "Steps in the training procedure include the following: • The compounder shall continually monitor the work of the employee and ensure that the employee's calculations and work are accurate and adequately performed." *Compounder in this reference means a pharmacist.*	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	6	d	Pharmacist responsibility for final preparation	USP Chapter 795 - "Steps in the training procedure include the following: • The compounder is solely responsible for the finished preparation." *Compounder in this reference means a pharmacist.*	
Compounding Process							
In the Rule References for Questions 7 -18 "compounder" can be either a pharmacist or a pharmacy technician, however the final check is the responsibility of a pharmacist.							
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	7		Do employees engaged in compounding check to ensure that the dose, safety, and intended use of the product or preparation has been evaluated for suitability?	USP Chapter <795> The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section. 1. The dose, safety, and intended use of the preparation or device has been evaluated for suitability in terms of: • the chemical and physical properties of the components • dosage form • therapeutic appropriateness and route of administration, including local and systemic biological disposition • legal limitations, if any.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8		Do employees engaged in compounding check ingredients to be used in the preparation have their expected identity, quality, and purity?	USP Chapter 795 - Compounding Process - "The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section. 3. Ingredients used in the formulation have their expected identity, quality, and purity. If the formulation is for humans, ingredients are not on a list of federally recognized drugs or specific drug products that have been withdrawn or removed from the market for safety or efficacy reasons (see www.FDA.gov) "	

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Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	9	Do employees engaged in compounding verify that formulations intended for human use or food producing animals are checked to ensure they are not on a list of prohibited items for use in these formulations?	USP Chapter 795 - Compounding Process - "The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section. 3. If the formulation is for food-producing animals, ingredients are not on a list of components prohibited for use in food-producing animals. Certificates of Analysis, when applicable, and MSDSs have been consulted for all ingredients used."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	10	Is the compounding area appropriately clean and sanitized?	USP Chapter 795 - "The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section. 4. Compounding is done in an appropriately clean and sanitized area dedicated to this activity (see the section Compounding Facilities)."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11	Are compounds prepared one at a time in a specific or dedicated workspace?	USP Chapter 795 - "The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section. 5. Only one preparation is compounded at one time in a specific workspace."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	12	Is compounding equipment inspected for cleanliness and proper functioning?	USP Chapter 795 - "The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section. 6. Appropriate compounding equipment has been selected and inspected for cleanliness and correct functioning and is properly used."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	13	Are appropriate BUDs assigned to finished preparations?	USP Chapter 795 - "The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section. 7. A reliable BUD is established to ensure that the finished preparation has its accepted potency, purity, quality, and characteristics, at least until the labeled BUD."	

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Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	14	Do employees engaged in compounding properly wash hands and wear the proper PPE based on the type of compounding performed?	USP Chapter 795 - "The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section. 8. Personnel engaged in compounding maintain good hand hygiene and wear clean clothing appropriate to the type of compounding performed (e.g., hair bonnets, coats, gowns, gloves, facemasks, shoes, aprons, or other items) as needed for protection of personnel from chemical exposures and for prevention of drug contamination."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	15	Are critical processes verified by a pharmacist during compounding to ensure expected qualities of the finished preparation?	USP Chapter 795 - "The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section. 10. Critical processes (including but not limited to weighing, measuring, and mixing) are verified by the compounder to ensure that procedures, when used, will consistently result in the expected qualities in the finished preparation."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	16	Is the final preparation assessed by a pharmacist using factors such as weight, adequacy of mixing, clarity, odor, color, consistency, pH, and analytical testing, as appropriate?	USP Chapter 795 - "The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section. 11. The final preparation is assessed using factors such as weight, adequacy of mixing, clarity, odor, color, consistency, pH, and analytical testing as appropriate; and this information is recorded on the Compounding Record."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	17	Is the final preparation properly labeled?	USP Chapter 795 - "The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section. 13. The preparation container is labeled according to all applicable state and federal laws. The labeling shall include the BUD and storage and handling information." *See RCW 18.64.246*	

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Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
Compounding Facilities						
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	18	Is there adequate space in the compounding facility that is also designated specifically for compounding to occur?	USP Chapter 795 - "Compounding facilities shall have an adequate space that is specifically designated for compounding of prescriptions."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	19	Do compounding facilities provide for placement of equipment and materials to avoid mix-ups among ingredients, containers, labels, in-process materials, and finished preparations and cross-contamination?	USP Chapter 795 - "This space shall provide for the orderly placement of equipment and materials to prevent mix-ups among ingredients, containers, labels, in-process materials, and finished preparations and is designed, arranged, and used to prevent adventitious cross-contamination."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	20	Are areas for non-sterile compounding and sterile compounding separate from each other?	USP Chapter 795 - "Areas used for sterile preparations shall be separated and distinct from the nonsterile compounding area."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	21	Is purified water used in compounding of nonsterile preparations?	USP Chapter 795 - "Purified Water (see Purified Water monograph) shall be used for compounding nonsterile drug preparations when formulations indicate the inclusion of water."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	22	Are adequate hand and equipment washing facilities easily accessible to the compounding area?	USP Chapter 795 - "Adequate hand and equipment washing facilities shall be easily accessible to the compounding areas. Such facilities shall include, but are not limited to, hot and cold water, soap or detergent, and an air-drier or single-use towels."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	23	Are all your compounding areas kept clean, and in good repair?	USP Chapter 795 - "The areas used for compounding shall be maintained in clean, orderly, and sanitary conditions and shall be maintained in a good state of repair."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	24	Is waste handled in accordance with local, state, and federal guidelines?	USP Chapter 795 - "Waste shall be held and disposed of in a sanitary and timely manner and in accordance with local, state, and federal guidelines."	

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Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	25	Are heating, ventilation, and air conditioning systems controlled to avoid decomposition and contamination of chemicals?	USP Chapter 795 - "Heating, ventilation, and air conditioning systems shall be controlled to avoid decomposition and contamination of chemicals (see the General Notices and Requirements, Preservation, Packaging, Storage, and Labeling, Storage Temperature and Humidity; and the manufacturers' labeled storage conditions)."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	26	Are all compounding components, equipment, and containers stored in accordance with the manufacturer or other specified conditions, off of the floor?	USP Chapter 795 - "All components, equipment, and containers shall be stored off the floor and in a manner to prevent contamination and permit inspection and cleaning of the compounding and storage area."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	27	Are hazardous drugs stored, prepared, and handled by trained personnel under conditions that protect all personnel?	USP Chapter 795 - "Hazardous drugs shall be stored, prepared, and handled by appropriately trained personnel under conditions that protect the healthcare workers and other personnel."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	28	Does disposal of hazardous drugs comply with all applicable federal and state regulations?	USP Chapter 795 - "Disposal of all hazardous drug wastes shall comply with all applicable federal and state regulations."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	29	Are all personnel who perform routine custodial waste removal and cleaning in hazardous drug preparation areas trained in appropriate procedure to protect themselves and prevent contamination?	USP Chapter 795 - "All personnel who perform routine custodial waste removal and cleaning activities in storage and preparation areas for hazardous drugs shall be trained in appropriate procedures to protect themselves and prevent contamination."	
Compounding Equipment						
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	30	Is equipment appropriate for use in compounding?	USP Chapter 795 "The equipment and utensils used for compounding of a drug preparation shall be of appropriate design and capacity....The equipment shall be of suitable composition that the surfaces that contact components are neither reactive, additive, nor sorptive and therefore will not affect or alter the purity of the compounded preparations."	

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Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	31	Is all equipment stored to protect it from contamination and located to facilitate use, maintenance and cleaning?	USP Chapter 795 - "Equipment shall be stored to protect it from contamination and shall be located to facilitate its use, maintenance, and cleaning."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	32	Are automated, mechanical, electronic, or other technology used in compounding routinely tested, inspected, and calibrated to ensure proper performance?	USP Chapter 795 - "Automated, mechanical, electronic, and other types of equipment used in compounding or testing of compounded preparations shall be routinely inspected, calibrated as necessary, and checked to ensure proper performance."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	33	Is equipment checked by employees engaged in compounding to determine its suitability for use in compounding?	USP Chapter 795 - "Immediately before compounding operations, the equipment shall be inspected by the compounder to determine its suitability for use." *Compounder in this reference can be either a pharmacist or a pharmacy technician.*	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	34	Is equipment used during compounding cleaned after use?	USP Chapter 795 - "After use, the equipment shall be appropriately cleaned."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	35	If the same equipment is being used for all drug products, are there procedures in place that allow meticulous cleaning of equipment before use with other drugs?	USP Chapter 795 - "... when the same equipment is being used for all drug products, appropriate procedures shall be in place to allow meticulous cleaning of equipment before use with other drugs."	
Component Selection, Handling, and Storage						
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	36	Are components used in compounding manufactured by FDA-registered facilities?	USP Chapter 795 - "The following guidelines shall be followed when selecting, handling, and storing components for compounded preparations. 2. Compounders shall first attempt to use components manufactured in an FDA-registered facility." *Compounder in this reference can be either a pharmacist or a pharmacy technician.*	

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Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	37	If components are not available from FDA- registered facilities, is professional judgment used when selecting components and to establish purity and safety by reasonable means?	USP Chapter 795 - "The following guidelines shall be followed when selecting, handling, and storing components for compounded preparations. 2. When components cannot be obtained from an FDA-registered facility, compounders shall use their professional judgment in selecting an acceptable and reliable source and shall establish purity and safety by reasonable means, which should include Certificate of Analysis, manufacturer reputation, and reliability of source." <i>*Compounder in this reference can be either a pharmacist or a pharmacy technician.*</i>	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	38	Do ingredients used in preparations meet the requirements of compendial monographs for those ingredients? <i>*See point 4 in rule reference column to the right, for when compendial quality components are not obtainable.*</i>	USP Chapter 795 - "The following guidelines shall be followed when selecting, handling, and storing components for compounded preparations. 3. Official compounded preparations are prepared from ingredients that meet requirements of the compendial monograph for those individual ingredients for which monographs are provided. These preparations may be labeled USP or NF as appropriate. 4. When components of compendial quality are not obtainable, components of high quality such as those that are chemically pure, analytical reagent grade, or American Chemical Society–certified may be used."	

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Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	39	<p>When components are transferred from an original container to a different container, is that container identified with:</p> <ul style="list-style-type: none"> - Component Name - Original Supplier - Lot or Control Number - Transfer Date, and - Expiration Date 	<p>USP Chapter 795 - "The following guidelines shall be followed when selecting, handling, and storing components for compounded preparations. 5. For components in containers that have an expiration date from the manufacturer or distributor, the material may be used in compounding before that expiration date (a) when the material is stored in its original container under conditions to avoid decom-position of the chemicals ... (b) when there is minimal exposure of the remaining material each time material is withdrawn from the container, and (c) when any withdrawals from the container are performed by those trained in the proper handling of the material. If the component has been transferred to a different container, that container shall be identified with the component name, original supplier, lot or control number, transfer date, and expiration date and shall provide integrity that is equivalent to or better than that of the original container."</p>	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	40	<p>When components do not have an expiration date assigned by the manufacturer/supplier, is the container labeled with date of receipt, and assigned a conservative expiration date that does not exceed 3 years from receipt?</p>	<p>USP Chapter 795 - "The following guidelines shall be followed when selecting, handling, and storing components for compounded preparations. 6. For components that do not have expiration dates assigned by the manufacturer or supplier, the compounder shall label the container with the date of receipt and assign a conservative expiration date, not to exceed three years after receipt, to the Component (see the General Notices and Requirements, Preservation, Packaging, Storage, and Labeling, Labeling, Expiration Date and Beyond-Use Date) based on the nature of the component and its degradation mechanism, the container in which it is packaged, and the storage conditions."</p>	

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Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	41	Are manufactured drug products used by your pharmacy as the source of active ingredient manufactured by FDA- registered facilities and is appropriately labeled with a batch control number and expiration date?	USP Chapter <795> The following guidelines shall be followed when selecting, handling, and storing components for compounded preparations. 7. If a manufactured drug product is used as the source of active ingredient, the drug product shall be manufactured in an FDA-registered facility, and the manufacturer's product container shall be labeled with a batch control number and expiration date.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	42	Does the compounder consider all ingredients, including excipients, present in the drug product relative to the intended use of the compounded preparation and the effect of manipulating the drug product on the therapeutic appropriateness and stability of the components?	USP Chapter 795 - "The following guidelines shall be followed when selecting, handling, and storing components for compounded preparations. 7 When compounding with manufactured drug products, the compounder shall consider all ingredients, including excipients, present in the drug product relative to the intended use of the compounded preparation and the effect of manipulating the drug product on the therapeutic appropriateness and stability of the components."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	43	Do ingredients used for dietary or nutritional supplements meet USP, FCC or NF standards?	USP Chapter 795 - "The following guidelines shall be followed when selecting, handling, and storing components for compounded preparations. 8. If the preparation is intended for use as a dietary or nutritional supplement, then the compounder must adhere to this chapter and must also comply with any federal and state requirements. Generally, dietary supplements are prepared from ingredients that meet USP, FCC, or NF standards. Where such standards do not exist, substances may be used in dietary supplements if they have been shown to have acceptable food-grade quality using other suitable procedures."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	44	Does your pharmacy receive written assurance from suppliers that components derived from ruminant animals are in compliance with federal laws?	USP Chapter 795 - "The following guidelines shall be followed when selecting, handling, and storing components for compounded preparations. 9. When a component is derived from ruminant animals (e.g., bovine, caprine, ovine), the supplier shall provide written assurance that the component is in compliance with all	

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					federal laws governing processing, use, and importation requirements for these materials."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	45	Are components used in compounding stored properly per manufacturer?	USP Chapter 795 - "All components used in the compounding of preparations must be stored as directed by the manufacturer, or according to USP, NF, or FCC monograph requirements, in a clean area, and under appropriate temperature and humidity conditions."	
Compliant						
Yes	No	N/A	#		Rule Reference	Notes/Corrective Actions
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	46	Are components used in compounding stored off the floor, handled and stored to prevent contamination, and rotated so that the oldest stock is used first?	USP Chapter 795 - "All components shall be stored off the floor, handled and stored to prevent contamination, and rotated so that the oldest stock is used first."	
Stability Criteria and Beyond-Use Dating						
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	47	Is the BUD determined from when the preparation is compounded?	USP Chapter 795 - "The BUD is the date after which a compounded preparation shall not be used and is determined from the date when the preparation is compounded."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	48	When assigning a BUD, are drug specific and general stability documents and literature consulted?	USP Chapter 795 - "When assigning a BUD, compounders shall consult and apply drug-specific and general stability documentation and literature when available ..."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	49	When a manufactured product is used as the source of the API for a nonsterile compounded preparation, does the compounder refer to the manufacturer, literature and stability factors to assign a beyond use date?	USP Chapter 795 - "When a manufactured product is used as the source of the API for a nonsterile compounded preparation, the product expiration date cannot be used solely to assign a BUD for the compounded preparation. The compounder shall refer to and consider the following: 1. Manufacturer for stability information 2. literature for applicable information on stability, compatibility, and degradation of ingredients"	

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					3. stability factors in USP <1191> All stability data shall be carefully interpreted in relation to the actual compounded formulation."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	50	Are preparations, at all steps in compounding, dispensing, and storage, observed for signs of instability and deterioration?	USP Chapter 795 - "At all steps in the compounding, dispensing, and storage process, the compounder shall observe the compounded drug preparation for signs of instability."	
compliant						
Yes	No	N/A	#		Rule Reference	Notes/Corrective Actions
Packaging and Drug Preparation Containers						
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	51	Do containers and closures used for packaging preparations meet USP requirements?	USP Chapter 795 - "The compounder shall ensure that the containers and container closures used in packaging compounded preparations meet USP requirements (see <659>; Containers—Glass <660>; Plastic Packaging Systems and their Materials of Construction <661>; Plastic Materials of Construction <661.1>; Plastic Packaging Systems for Pharmaceutical Use <661.2>; Containers—Performance Testing <671>; <1136>); and when available, compounding monographs..... Container suppliers shall supply, upon request, verification of USP container compliance." *Compounder in this reference can be either a pharmacist or a pharmacy technician, however the final check is the responsibility of a pharmacist.*	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	52	Are the containers and closures used for packaging preparations made of suitable clean material?	USP Chapter 795 - "The containers and closures shall be made of suitable clean material in order not to alter the quality, strength, or purity of the compounded drug preparation. The container used depends on the physical and chemical properties of the compounded preparation."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	53	Are the containers and closures used for packaging preparations stored appropriately off the floor in way to prevent contamination and rotated?	USP Chapter 795 - "The containers and closures shall be stored off the floor, handled and stored to prevent contamination, and rotated so that the oldest stock is used first."	

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<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	54	Are the containers and container closures stored in such a way as to permit inspection and cleaning of the storage area?	USP Chapter 795 - "The containers and container closures shall be stored in such a way as to permit inspection and cleaning of the storage area."	
Compliant					Rule Reference	Notes/Corrective Actions
Yes	No	N/A	#			
Compounding Documentation						
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	55	Does the compounder compound preparation in any other way than the manufacture's labeling instructions?	USP Chapter 795 "When the compounder compounds a preparation according to the manufacturer's labeling instructions, then further documentation is not required. All other compounded preparations require further documentation as described below. This includes a master formulation and compounding record." <i>*Compounder in this reference can be either a pharmacist or a pharmacy technician, however the final check is the responsibility of a pharmacist.*</i>	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		If yes to Question 55, does the Master Formula contain?	USP Chapter <795> "When the compounder compounds a preparation according to the manufacturer's labeling instructions, then further documentation is not required. All other compounded preparations require further documentation as described below. This includes a master formulation and compounding record." <i>*Compounder in this reference can be either a pharmacist or a pharmacy technician, however the final check is the responsibility of a pharmacist.*</i>	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	56	a Official or assigned name, strength, and dosage form of the preparation	USP Chapter 795 "this record shall include: Official or assigned name, strength, and dosage form of the preparation."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		b Calculations needed to determine and verify quantities or components and doses of active pharmaceutical ingredients	USP Chapter 795 "this record shall include; calculations needed to determine and verify quantities or components and doses of active pharmaceutical ingredients."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		c Description of all ingredients and their quantities	USP Chapter 795 "this record shall include: description of all ingredients and their quantities."	

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Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		d	Compatibility and stability information, including references when available	USP Chapter <795> "this record shall include: compatibility and stability information, including references when available."
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		e	Equipment needed to prepare the preparation, when appropriate	USP Chapter <795> "this record shall include: equipment needed to prepare the preparation, when appropriate."
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	56	f	Mixing instructions	USP Chapter 795 "this record shall include: Mixing instructions that should include order of mixing, mixing temperatures and environmental controls, duration of mixing, other factors pertinent to the replication of the preparation as compounded."
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		g	Container used in dispensing	USP Chapter 795 "this record shall include: container used in dispensing."
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		h	Packaging and storage requirements	USP Chapter 795 "this record shall include: packaging and storage requirements."
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		i	A description of the final preparation	USP Chapter 795 "this record shall include: description of the final preparation."
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		j	Quality control procedures and expected results	USP Chapter 795 "this record shall include: Quality control procedures and expected results."
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	57		<p>If yes to Question 55, does the Compounding Formula contain?</p> <p>USP Chapter 795 "When the compounder compounds a preparation according to the manufacturer's labeling instructions, then further documentation is not required. All other compounded preparations require further documentation as described below. This includes a master formulation and compounding record."</p> <p>*Compounder in this reference can be either a pharmacist or a pharmacy technician, however the final check is the responsibility of a pharmacist.*</p>	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		a	Official or assigned name, strength, and dosage of the preparation	USP Chapter 795 "this record shall include: official or assigned name, strength, and dosage of the preparation."
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		b	Master formula Record reference for the preparation	USP Chapter 795 "this record shall include: Master formula Record reference for the preparation."

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Compliant			#			Rule Reference	Notes/Corrective Actions
Yes	No	N/A					
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		c	Names and quantities of all components	USP Chapter 795 "this record shall include: names and quantities of all components."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		d	Sources, lot numbers, and expiration dates of all components	USP Chapter 795 "this record shall include: sources, lot numbers, and expiration dates of all components."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		e	Total quantity compounded	USP Chapter 795 "this record shall include: total quantity compounded."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	57	f	Name of the person who prepare the preparation, name of the person who performed the quality control procedures, and the name of the compounder who approved the preparation	USP Chapter 795 "this record shall include: Name of the person who prepare the preparation, name of the person who performed the quality control procedures, and the name of the compounder who approved the preparation."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		g		USP Chapter 795 "this record shall include: date of preparation."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		h	Control or prescription number	USP Chapter 795 "this record shall include: assigned control or prescription number."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		i	Assigned BUD	USP Chapter 795 "this record shall include: assigned BUD."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		j	Duplicate label described in the Master Formulation Record	USP Chapter 795 "this record shall include: duplicate label as described in the Master Formulation Record."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		k	Description of final preparation.	USP Chapter 795 "this record shall include: description of the final preparation."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		l	Results of the quality control procedures	USP Chapter 795 "this record shall include: results of the quality control procedures (e.g., weight range of filled capsules, pH of aqueous liquids)"	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		m	Documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or the caregiver	USP Chapter 795 "this record shall include: documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or the caregiver."	

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<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	58	Are Safety Data Sheets readily accessible to all employees working with drug substances or bulk chemicals located on the compounding facility?	USP Chapter 795 - "Material Safety Data Sheets (MSDSs) shall be readily accessible to all employees working with drug substances or bulk chemicals located on the compounding facility premises."	
Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
Quality Control						
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	59	Do pharmacists supervising compounding activities perform a final check that reviews each procedure used in the compounding process and observe the finished preparation to ensure it appears as expected?	USP Chapter 795 - "As a final check, the compounder shall review each procedure in the compounding process. To ensure accuracy and completeness, the compounder shall observe the finished preparation to ensure that it appears as expected and shall investigate any discrepancies and take appropriate corrective action before the prescription is dispensed to the patient." <i>*Compounder in this reference means a pharmacist.*</i>	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	60	Are controls in place to ensure compounding accuracy?	USP Chapter 795 - Compounding Controls "1. The Master Formulation Record, the Compounding Record, and associated written procedures shall be followed in execution of the compounding process. Any deviation in procedures shall be documented. 2. The compounder shall check and recheck each procedure at each stage of the process. If possible, a trained second person should verify each critical step in the compounding process. 3. The compounder shall have established written procedures that describe the tests or examinations conducted on the compounded preparation (e.g., the degree of weight variation among capsules) to ensure their uniformity and integrity. 4. Appropriate control procedures shall be established to monitor the output and to verify the performance of compounding processes and equipment that may be responsible for causing variability in the final compounded preparations." <i>*Compounder in this reference can be either a pharmacist or a pharmacy technician, however the final check is the responsibility of a pharmacist.*</i>	

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Compliant			#	Rule Reference	Notes/Corrective Actions
Yes	No	N/A			
Compounding for Animal Patients					
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	61	Do you compound products for animal patients? *If no, you do not need to answer the questions below.*	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	62	Is the intended use by the animal determined prior to compounding preparation?	USP Chapter 795 - "Intended use of any animal patient (e.g., companion, performance, food) shall be determined before compounding for that patient."
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	63	Do employees engaged in compounding for animals have knowledge of drug regulation and disposition for animal patients?	USP Chapter 795 - "All compounders preparing formulations for animals shall possess a functional knowledge of drug regulation and disposition in animal patients." *Compounder in this reference can be either a pharmacist or a pharmacy technician.*
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	64	Do labels include withdrawal time lengths for animals that are food-producing?	USP Chapter 795 - "Veterinarians are required by law to provide food-producing animal caregivers with an accurate length of time to withhold treated animal tissues (e.g., meat, milk, eggs) from the human food supply. This length of time is referred to as a withdrawal time (WDT) and must also, by law, be included on the dispensing label of every prescription prepared for a food-producing species."
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	65	Do your pharmacists have knowledge of individual species' limitations in physiology and metabolic capacities? What are your resources?	USP Chapter 795 - "The pharmacist shall be knowledgeable about the individual species' limitations in physiology and metabolic capacity that can result in toxicity when certain drugs or excipients are used in compounded preparations."